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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/538,821	03/30/2000	Douglas W. Morck	1506.63818	8331

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EXAMINER

CONLEY, SEAN E

ART UNIT

PAPER NUMBER

1744

7

DATE MAILED: 11/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/538,821

Applicant(s)

MORCK ET AL.

Examiner

Sean E Conley

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1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on October 4, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 13-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on March 30, 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-12, drawn to apparatus for sterilizing medical instruments, classified in class 422, subclass 298.
 - II. Claim 13-37, drawn to method of sterilizing an apparatus for medical instrument sterilization, classified in class 422, subclass 26.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus claimed by the applicant can be used to practice another materially different process. The apparatus of Group I can be used to prevent any number of diseases from spreading to patients. Steam sterilization of medical instruments is a well-known technique and is the primary means for sterilizing medical instruments. More specifically, the process of group II is directed to sterilizing the apparatus of Group I for the purpose of reducing the outbreak of diffuse lamellar keratitis (DLK) which results from eye surgery. However, the apparatus claimed in

Group I could be sterilized using a different process in order to prevent a number of other biological or bacterial outbreaks such as hepatitis B and tuberculosis.

3. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.

4. Applicant's election of Group I with traverse in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The restriction requirement has been reviewed and is still deemed proper and therefore made FINAL. Applicant is reminded to cancel the non-elected claims.

Priority

5. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Canada on October 22, 1999. It is noted, however, that applicant has not filed a certified copy of the application CA 2,287,150 as required by 35 U.S.C. 119(b).

Claim Objections

6. Claims 2 and 3 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Specifically, claims 2 and 3 are directed to the intended use of the apparatus and not the apparatus itself as claimed in claim 1. Therefore, claims 2 and 3 do not further limit the patentable subject matter of claim 1. The intended use of the apparatus in claim 1 is for reducing outbreaks of aseptic inflammations of the eye resulting from eye surgery. However, the intended use is not given patentable weight.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "manufactured from a substance which can be subjected to sufficiently high temperatures to destroy endotoxins" is improper. The phrase is indefinite because the applicant has disclosed the limitation "can be subjected" which may or may not be required to make the invention. Is the reservoir subjected to high temperatures? Or is it not?

Further, the phrase "sufficiently high temperature" is indefinite because a specific material has not been disclosed by the claim. What is considered a sufficiently high temperature for heating a substance? What is the substance? The claim does not limit

the material being subjected to high temperature and one cannot determine from the claim what is considered a sufficiently high temperature for treating a substance.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 9, 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newman (U.S. Pat. 5,271,893) in view of Sutter et al. (U.S. Pat. 5,543,119).

Newman discloses an apparatus for steam sterilization of articles (see figure 1). The apparatus comprises a sterilizer for sterilizing medical or dental instruments with steam. The apparatus includes a container (30) which is filled with distilled water and the water is pumped via dispensing pump (26) to boiler (20) where the steam is generated. The generated steam is then supplied to the pressure chamber (10) to sterilize the medical and dental instruments (see column 4, line 14 to column 5, line 48). Furthermore, the apparatus is adapted to be contained within a relatively small and lightweight bench top unit (see column 1, lines 59-61).

However, the apparatus of Newman does not specifically disclose that the distilled water container is separable from the housing.

Sutter et al. disclose an apparatus for treatment of medical and dental instruments with steam. The apparatus (1) comprises a housing which includes a treatment chamber (2) for housing the medical and dental instruments to be treated with steam. A container (7) filled with distilled water supplies the steam generator (45) which makes the steam that is used to treat the instruments. The container (7) is an inverted bottle which is located adjacent an upper surface of the housing and is connected to a filling opening (6). The housing further comprises a door or lid (7b) which can close the notch that receives the container (7) once it has been inserted (see

column 2, lines 29-50). The container (7) is separable from the housing and disposable. When the door is being used the distilled water container is internal to the housing and when the door is not used the bottle is located external to the housing (see figure 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Newman and replace the distilled water holding means (internal reservoir) with the means of Sutter et al. (inverted and removable internal/external bottle) in order to provide easy access to the container when it needs replacing.

13. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Newman in view of Sutter et al. as applied to claim 1 and further in view of Polk (U.S. Pat. 3,734,154).

Newman and Sutter et al. do not teach a distilled water reservoir which is in the form of a bag.

Polk discloses a disposable bag with a self closing valve. The bag is used for containing and dispensing liquids such as water (see figure 1 and column 1, lines 7-10). This reference has been relied upon to teach that it is known to dispense water from a reservoir which is a bag.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the invention of Newman and replace the

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reservoir means (inverted bottle) with the means of Polk (disposable bag) because a bag is functionally equivalent to a bottle.

14. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Newman in view of Sutter et al. as applied to claim 1 and further in view of Murphy et al. (U.S. Pat. 5,972,196).

Newman and Sutter et al. do not teach or disclose the material used to make the distilled water containers.

Murphy et al. teach a method of sterilizing medical instruments using humidified ozone. The apparatus comprises a water reservoir, which is made of Pyrex glass (see column 17, line 59-60). The reference has been relied upon to teach that it is known to make a water reservoir out of Pyrex glass.

Although Newman and Sutter et al. do not specifically recite the material of the reservoir, modifying the material would have been obvious at the time of the applicant's invention because of the legal precedent In re Aller, 105 USPQ 233 (CCPA 1955) which states that the use of preferred materials discovered by routine experimentation is ordinarily within the skill of the art.

Furthermore, it would have been obvious in view of the water reservoir taught by Murphy et al. to make the water reservoir out of a material such as Pyrex glass.

15. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Newman in view of Sutter et al. as applied to claim 1 and further in view of Black (U.S. Pat. 3,717,434).

Newman and Sutter et al. do not teach or disclose the material used to make the distilled water containers.

Black discloses an autoclave adapted for use as a sterilizer. The autoclave generates steam which is supplied to a sterilizing chamber where instruments are to be treated. The apparatus comprises a condenser chamber (22) which serves as a reservoir for feed water to be returned to the steam-generating chamber (see figure 5 and column 5, line 54-56). The reservoir (22) is formed from corrosion resistant metal such as stainless steel because the various chambers of the apparatus come into contact with water and steam which are the cause of the corrosion.

Although Newman and Sutter et al. do not specifically recite the material of the reservoir, modifying the material would have been obvious at the time of the applicant's invention because of the legal precedent In re Aller, 105 USPQ 233 (CCPA 1955) which states that the use of preferred materials discovered by routine experimentation is ordinarily within the skill of the art.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the invention of Newman and form the distilled water reservoir (bottle) out of stainless steel in order to prevent corrosion as taught by Black.

16. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Newman in view of Sutter et al. as applied to claim 1 and further in view of Hestehave et al. (U.S. Pat. 4,548,344).

Newman and Sutter et al. do not teach a distilled water reservoir which comprises a hollow vessel having a threaded neck to sealingly receive a threaded cap provided with a means to receive a tube.

Hestehave et al. disclose an adaptor assembly for storage drums and cans. The adapter assembly (1) is designed to enable pumping of liquids from large vessels (D) having openings that are sealable by threaded closures. The adapter itself (1) comprises a threaded cap (3) designed to be mated to the mouth of the container. The cap (3) has a means to receive a tubing (5) which is used to pump the liquid from the container (see figure 1 and 2, column 3, lines 20-51). The invention of Hestave et al. is not limited to only dispensing fuel. It is disclosed that the assembly can be used for dispensing any liquids.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the invention of Newman and replace the external reservoir with a reservoir taught by Hestehave et al. in order to supply the distilled water from a remote location separate from the housing. Also, it would have been obvious to replace the reservoir of Newman with the fluid dispenser of Hestave et al. because they are functionally equivalent in that they both are used to dispense a liquid.

17. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Newman in view of Sutter et al. as applied to claim 1 and further in view of Herr (U.S. Pat. 5,671,868).

Newman and Sutter et al. do not teach or disclose an inverted reservoir that includes an air release valve, which is opened when the system is operating.

Herr discloses a fluid-dispensing container (1) equipped with a folding spout (5), a handle (15) and a refilling cap (16) provided with an air release valve (17). The air release valve controls the fluid flow when the container is inverted and the fluid is dispensed (see figures 1, 3, 5, 10 and column 6, lines 52-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the invention of Newman and add an air release valve to the inverted distilled water bottle in order to control the fluid flow rate from the container as taught by the fluid dispensing device of Herr.

18. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Newman in view of Sutter et al. as applied to claim 1 and further in view of DE 3103381 A1.

Newman and Sutter et al. do not disclose a distilled water reservoir which is independent from the housing.

DE 3103381 A1 discloses an apparatus for sterilizing medical instruments with steam. The apparatus comprises a pressure chamber (1) with an evaporator (50) for generating steam. The reservoir (22) which is separate and independent from the housing is filled with distilled water which is supplied to the evaporator and used to

generate the steam required to treat the instruments (see figures, based on oral translation).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the invention of Newman and replace the external reservoir on the housing with a separate, independent housing as taught by the invention of DE 3103381 A1 in order to provide a reservoir that can be placed anywhere to make it easily accessible to be refilled or replaced.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. 4,263,258 A to Kalasek

U.S. Pat. 6,363,979 B1 to Chafin et al.

U.S. Pat. 5,424,047 A to Zwingenberger et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Conley, whose telephone number is (703) 305-2430. The examiner can normally be reached on Monday-Friday 7:30 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Robert Warden, can be reached at (703) 308-2920. The Unofficial fax phone number for this group is (703) 305-7719. The Official fax phone number for this Group is (703) 872-9310.


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Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [robert.warden@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist, whose telephone number is (703) 308-0661.

SEC

October 31, 2002


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